DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 9, 2015

Westridge Laboratories, Inc.
Albert Rego, Ph.D.
Regulatory Consultant
27001 La Paz Road, Suite 312
Mission Viejo, CA 92691

Re: K141767
Trade/Device Name: ID® Millennium®, ID® Moments® Silicone
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: February 21, 2015
Received: February 23, 2015

Dear Albert Rego,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141767

Device Name
ID® Millennium® , ID® Moments® Silicone

Indications for Use *(Describe)*

ID® Millennium® is a personal lubricant, for penile and /or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

ID® Moments® Silicone is a personal lubricant, for penile and /or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary

Submitted by:

Westridge Laboratories, Inc.
1671 E. Saint Andrew Place
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Contact Person:

Robert Grant
Quality & Regulatory Affairs Manager
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Date Prepared:

Propriety Name: ID® Millennium Personal Lubricant

Proposed Trade Name: ID® Millennium Personal Lubricant

Common Name: Personal Lubricant

Classification Name:

Condoms
21 CFR 884.5300 Class II
NUC

Predicate Device:

Wet Platinum Premium Lubricant®
510(K) No. (K130012)

Device Description:

ID® Millennium® is non-sterile, an over-the-counter silicone based personal lubricant, formulated to be clear, non-irritating, non-greasy natural and odorless. This device is silicone soluble liquid for use as a personal lubricant. ID® Millennium® Personal Lubricant contains a blend of silicone fluid ingredients similar to ingredients found in the predicate device. ID® Millennium® Personal Lubricant is neither a contraceptive nor a spermicide.

The device is available in the following variant personal lubricant formulas:
ID® Millennium® and ID Moments® Silicone.

ID® Millennium® Personal Lubricant is provided in plastic/PET bottles with screw-on cap, flip top closure, pump dispensers, and foils.

Intended Use:

ID® Millennium® Personal Lubricant is non-sterile, over-the-counter personal lubricant. This device is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

510(K) Summary

Indications for Use:

ID® Millennium®:
ID® Millennium® is a personal lubricant, for penile and /or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

ID® Moments® Silicone:
ID® Moments® Silicone is a personal lubricant, for penile and /or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

ID® Millennium® Personal Lubricant and predicate device have the same Indications for Use Statement.

Technological Characteristics:

There are no differences in the fundamental technological characteristics of ID® Millennium ® Personal Lubricant and predicate Wet Platinum Premium Lubricant®. ID® Millennium® Personal Lubricant consists mainly of silicone; it contains a blend of silicone fluid ingredients similar to other lubricants currently on the U.S. markets and is substantially equivalent to the predicate device. ID® Millennium® Personal Lubricant formula is neither a contraceptive nor a spermicide.

BIOCOMPATIBILITY:

As with the predicate, testing for cytotoxicity, vaginal irritation, sensitization, and systemic toxicity demonstrate that the device is biocompatible.

Testing Performed	Standard Reference #	Results
Cytotoxicity (Agar Overlay)	ISO 10993-5:2009	The device is not cytotoxic
ISO Guinea Pig Maximization Sensitization	ISO 10993-10:2010	The device is non-sensitizing
Vaginal Irritation and Systemic Toxicity Study Following Repeated Exposure in Rabbits (The study utilizes FDA recommended hybrid ISO Irritation / Acute Systemic Toxicity test)	ISO 10993-10:2010 ISO 10993-11:2006	The device is not an irritant and not systemically toxic.

510(K) Summary

Specifications:

ID® Millennium line of products has the following specifications: viscosity, specific gravity, appearance, color and odor, absence of pathogenic organisms (Pseudomonas aeruginosa, Staphylococcus aureus, and Candida albicans) per USP <62>, total aerobic microbial count , and total yeast and mold count per USP <61> and <1111>, and water activity test per USP <1112>.

Condom Compatibility:

Condom Compatibility Testing was performed in accordance with ASTM 7661-10 on major brand name latex, polyurethane, and polyisoprene condoms.

The condom compatibility testing demonstrate that ID® Millennium® lubricants are compatible with commercially available male condoms made from natural rubber latex, polyurethane, and polyisoprene materials.

Shelf Life Testing:

ID® Millennium Personal Lubricant has three year shelf-life. Retains were obtained and tested per Westridge Laboratories, Inc. specifications.

Conclusion:

ID® Millennium® Personal Lubricant has the same intended use and basic technological characteristics as the predicate device and is as safe and effective as its predicate device. Therefore, ID® Millennium Personal Lubricant is substantially equivalent to the predicate device.